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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/802,686

03/09/2001

Gary Van Nest

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755 PAGE MILL RD

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EXAMINER

LE, EMILY M

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/802,686	<b>Applicant(s)</b> VAN NEST, GARY	
	<b>Examiner</b> EMILY M. LE	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8-10,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-10,16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Status of Claim(s)*

1. Claims 2, 6-7, 11-15 and 18 are cancelled. Claims 1, 3-5, 8-10 and 16-17 are pending and under examination.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 8-10 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al.<sup>1</sup>

4. The claims are directed to a process comprising the administration of a composition to the respiratory tract of an individual by local administration, wherein said composition comprises a polynucleotide comprising an immunostimulatory sequence comprising the TCG motif, wherein the ISS sequence is greater than 6 and less than about 50 nucleotides in length, wherein the individual is a human and the composition is administered between 3 and 14 days before exposure to RSV. Claim 3, which depends on claim 1, requires that the ISS comprises the sequence purine-purine-CG-pyrimidine-pyrimidine. Claim 8, which depends on claim 1, requires that administration be to the

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<sup>1</sup> Wagner et al. U.S. PreGrant Publication No. 2004/0030118, which is a continuation of 09/241653, which was filed on 02/02/1999.

lung. Claim 9, which depends on claim 1, requires the administration be directed to the nasal passages. Claim 10, which does not further limit the claimed invention, specifies that the suppression of RSV by performing the claimed method comprises a reduction of RSV titer in a biological sample from said individual. Claim 16, which depends on claim 1, requires that the polynucleotide to comprise a phosphate backbone modification.

Wagner et al. teaches a process comprising the administration of a composition to the respiratory tract of a subject by local administration, wherein said composition comprises a polynucleotide comprising an immunostimulatory sequence (ISS) comprising the TCG motif, wherein the ISS sequence is greater than 6 and less than about 50 nucleotides in length, wherein the composition is administered between 3 and 14 days before exposure to RSV. [Claims 19-36, in particular.] By "subject", Wagner et al. includes humans. [Paragraph 0093, in particular.] . The ISS that Wagner et al. teaches encompass those having the sequence purine-purine-CG-pyrimidine-pyrimidine. [Sequence listing, in particular.] Wagner et al. teaches that the administration be intranasal, the nasal passages and to the lungs, and that the polynucleotide have comprise a phosphate backbone modification.

In the instant case, Wagner et al. teaches a process that is the same as the claimed invention. Therefore, Wagner et al. anticipates the claimed invention.

While it is noted that the preamble and wherein clause of the claims require that the method suppresses or reduces RSV titer, it should be noted that such requirement do not further limit the claims. Said preamble and wherein clause do not impart any

additional functional or structural characteristic onto the claimed invention. Therefore, neither are interpreted as a limitation. Additionally, it should be noted that the Wagner et al. does not need to appreciate the RSV suppressive activity described by Applicant in order to anticipate the claimed invention for such would have been inherent of the method taught by Wagner et al. Since the method of Wagner et al. is the same as the claimed method, the method of Wagner et al. would also necessarily suppress or reduce RSV titer. MPEP 2112, which provides "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al., as applied to claims 1 and 3, in view of Raz, E.<sup>2</sup>

Claim 4, which depends on claim 3, requires that the ISS comprises the sequence AACGTTTCG or GACGTTTCG. Claim 5, which depends on claim 1, requires

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<sup>2</sup> Raz, E. U.S. PreGrant Publication No. 2003/0092663, which has priority to U.S. Patent No. 6498148, which was filed 01/21/1999.

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the polynucleotide to comprise the following sequence:

TGACTGTGAACGTTTCGAGATGA (SEQ ID NO: 1).

Wagner et al. does not teach a polynucleotide comprising the following: TGACTGTGAACGTTTCGAGATGA. However, Wagner et al. does suggest the use of polynucleotide comprising the CpG motif. At the time the invention was made, Raz, E. teaches a polynucleotide comprising TGACTGTGAACGTTTCGAGATG, which Raz, E. designates as SEQ ID NO: 19. Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use the polynucleotide of Raz, E. as an alternative to the polynucleotide used by Wagner et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to induce an immune response in the subject. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the substitution of known alternatives is routinely practiced in the art.

7. Claims 1 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al., as applied to claim 1.

Claim 17, which depends on claim 1, requires that the composition comprises a pharmaceutically acceptable excipient.

Wagner et al. did not administer the composition with a pharmaceutically acceptable excipient, Wagner et al. does suggest the use of pharmaceutically acceptable excipients to facilitate delivery of the drug. Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to include a pharmaceutically acceptable excipient with the composition of Wagner et al.

One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate the delivery of the composition. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the use of pharmaceutically acceptable excipients with compositions is routinely practiced in the art.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. The double patenting rejection over U.S. Patent Application No. 10/426237 is withdrawn in view of the abandonment of the cited patent application.

10. The double patenting rejection over U. S Patent No. 10/898512 is maintained for reason(s) set forth in the record. It is noted that Applicant has stated that Applicant will address this provisional double patenting rejection with a terminal disclaimer.

Applicant's intention is noted. Until the rejection is properly addressed with a terminal disclaimer, the rejection is maintained on the record.

### ***Conclusion***

11. No claim is allowed. To allow the entry of the rejection set herein, the office action is non-final.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/  
Primary Examiner, Art Unit 1648

/E. M. L./